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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,096	10/14/2004	Heinz Von der Kammer	P67813US1	6145

136 7590 07/16/2007

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EXAMINER	
POPA, ILEANA	

ART UNIT	PAPER NUMBER
1633	

MAIL DATE	DELIVERY MODE
07/16/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/511,096	VON DER KAMMER ET AL.	
	Examiner	Art Unit	
	Ileana Popa	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 April 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-25* is/are pending in the application.

4a) Of the above claim(s) *22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21 and 23-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in the prior Office Action.

2. Claims 1-20 have been cancelled. Claims 21-25 are new. The new claims 21 and 23-25, drawn to a recombinant non-human animal comprising a non-native nucleic acid sequence encoding for golgin-245 and to a method of using the transgenic non-human animal in a method of screening for agents that modulate Alzheimer's disease, are encompassed by the elected invention.

Newly submitted claim 22 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the new claims 22 is drawn to a method of using the recombinant non-human animal of claim 21 for diagnosing Alzheimer's disease, whereas the elected invention is drawn to a method of screening for a modulator of Alzheimer's disease.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 22 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 21 and 23-25 are under examination.

3. All rejection set forth in the non-final Office action of 11/14/2006 are withdrawn because Applicant cancelled all claims subject to the rejections in the response filed on 04/16/2007.

New Rejections

Claim Rejections - 35 USC § 101

4. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. Claims 21 and 23-25 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or well established utility. Applicant is referred to the utility guidelines published in Federal Register January 5, 2001, Volume 66, Number 5, page 1092-1099.

Since claims 21 and 23-25 are encompassed by the elected invention, the rejection under 35 U.S.C. 101 as set forth in the non-final Office action of 11/14/2006 for claims 11-15 is presented again.

Applicant argues that the specification teaches the detection and disregulation of transcripts encoding for golgin-245 in human brain samples taken from Alzheimer's patients as compared to age matched normal brains and therefore, this link provides for the diagnosis and the treatment of Alzheimer's disease (AD). Applicant argues that the Examiner failed to demonstrate that that the instant invention lacks utility. Applicant submits that, since the specification teaches that there is a correlation between golgin-245 disregulation in the brain and AD, the utility requirement is satisfied. Additionally,

applicant argues that the references cited by the Examiner rather point out the difficulties and need for further research in the area, however and therefore, they do not contradict the utility of the invention. Applicant concludes that such references serve to demonstrate the patentability of the claimed invention because they show that one of ordinary skill in the art would not have expected the instant invention.

Applicant's arguments are acknowledge, however, the rejection is maintained for the reasons of record set forth in the non-final Office action. The specification clearly teaches that to date there is no experimental data demonstrating a relationship between over-expression of golgin-245 and any neurodegenerative disease (p. 3, paragraph 13). An updated search in the patent and non-patent literature failed to provide any role for golgin-245 in AD. Disclosing identifying, by differential display, that golgin-245 mRNA is over-expressed in the brain samples taken from patients affected with Alzheimer's disease as opposed to normal, age matched subjects (p.3, paragraph 13) is not evidence that golgin-245 plays a role in AD. Identifying, by differential display that the golgin-245 transcript is overexpressed is not evidence that overexpression occurs before the onset of AD (i.e., that golgin-245 plays a role in AD pathogenesis); golgin-245 transcript might be upregulated as a consequence of the AD. In fact, the art teaches that golgin-245 is overexpressed in a variety of pathological conditions other than AD (see also the non-final Office action). Therefore, over-expression of golgin-245 is more likely to be an unspecific event, rather than a disease causative event. In effect, because the function of the protein is not known and its correlation with AD is not proven, the cells or transgenic non-human animals and hence, the screening method for

a modulator of AD, are not of use, as the function of the protein itself is not known and, most importantly, there is no evidence of a phenotype for a transgenic animal overexpressing golgin-245 or that the over-expression of gogin-245 is the cause of AD. It is noted that the specification does not provide any example of transgenic animal and therefore, the phenotype is predicted; however there is no evidence in the specification or the art that a transgenic animal overexpressing golgin-245 develops AD. With respect to Applicant's arguments regarding the references cited by the Examiner, it is noted that the all references teach that further experimentation is required to define a role for golgin-245 (i.e., a "real world" use), which is evidence that the instant invention lacks specific and substantial utility.

Claim Rejections - 35 USC § 112, enablement

6. Claims 21 and 23-25 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed inventions are not supported by either a credible asserted utility or a well-established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention so that it will operate as intended without undue experimentation.

Claim Rejections - 35 USC § 112, written description

7. Claims 21 and 23-25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one

skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Since claims 21 and 23-25 are encompassed by the elected invention, the rejection under 35 U.S.C. 112, first paragraph, written description as set forth in the non-final Office action of 11/14/2006 for claims 11-15 is presented again.

It is noted that Applicant did not present any argument to traverse the instant rejection, other than that the rejection is based on the same reasoning as the 101 rejection and therefore, it falls with the 101 rejection.

The rejection is maintained for the reasons set forth in the non-final Office action (it is noted that the reasoning for the instant rejection is not the same with that for the 101 rejection).

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ileana Popa whose telephone number is 571-272-5546. The examiner can normally be reached on 9:00 am-5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ileana Popa, PhD

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